

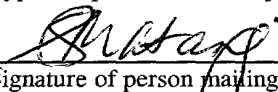
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(Signature of person mailing paper or fee)

Patent

Attorney's Docket No. 033388-371

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Reissue Application of ) BOX REISSUE  
U.S. Patent No. 5,965,159 )  
MAYHEW, et al. ) Group Art Unit: Unassigned  
Application No.: Unassigned ) Examiner: Unassigned  
Filed: Herewith )  
For: ETHERLIPID-CONTAINING )  
MULTIPLE LIPID LIPOSOMES )

**DECLARATION**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We, Eric Mayhew, Andrew S. Janoff, Imran Ahmad, and Suresh Bhatia, the above-named inventors, hereby declare that:

1. I, Eric Mayhew, am a citizen of the United Kingdom, and my residence is 26 Allison Court, Monmouth Junction, New Jersey 08852;  
I, Andrew S. Janoff, am a citizen of the United States, and my residence is 560 Countess Drive, Yardley, Pennsylvania 19067;  
I, Imran Ahmad, am a citizen of India, and my residence is 12 Pinehurst Drive, Cranbury, New Jersey 08512;

I, Suresh K. Bhatia, am a citizen of India, and my residence is  
F13 Tara Apartments, Alaknanda, New Delhi 110019, India.

2. That we believe that we are the original and first inventors of the subject matter which is claimed in this application for reissue and for which reissue of the original Letters Patent on the invention entitled "ETHERLIPID-CONTAINING MULTIPLE LIPID LIPOSOMES" is sought.

3. That we have reviewed and understand the contents of the specification and claims of the above-identified reissue patent application, and that this specification and claims are attached to this declaration.

4. That we do not know and do not believe that said invention was ever known or used in the United States of America before our invention thereof.

5. That we acknowledge the duty to disclose to the Patent Office all information known to us to be material to the patentability of this reissue application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

6. That we believe the original patent to be partly inoperative or invalid by reason of claiming less than we had a right to claim in the patent. More specifically, such deficiencies in the claims include the failure to include a claim of the scope of new claim 17 which recites a liposome composition of a) a phosphatidylcholine b) a sterol c) a head group derivatized lipid and d) an etherlipid in which the Z component of the etherlipid of the claimed liposome may be an amine, an amide or a carboxylic acid. Support for these Z groups may be found at least at column 4, lines 22-26. Support for the phosphatidylcholine may be found at least at column 4 lines 55 - 59. Support for the sterol may be found at least at column 4 lines 60 - 67. Support for the head group derivatized lipid may be found at least at column 5 line 1 - column 6 line 52.

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New dependent claim 18 recites a unilamellar liposome with a diameter of  $\sim 50$  nm to  $\sim 200$  nm. Support for unilamellar liposomes with this diameter may be found at least at column 3 lines 43 - 46.

New dependent claim 19 recites unsaturated or partially unsaturated phosphatidylcholine. Support for unsaturated or partially unsaturated phosphatidylcholine may be found at least at column 4 lines 55 - 58.

New dependent claim 20 recites that phosphatidylcholine is dioleoyl phosphatidylcholine. Support for dioleoyl phosphatidylcholine may be found at least at column 4 lines 58 - 59.

New dependent claim 21 recites that the sterol is cholesterol. Support for cholesterol may be found at least at column 4 lines 64 - 67.

New dependent claim 22 recites headgroup derivatized lipid that comprises a phosphatidylethanolamine selected from dipalmitoyl phosphatidylethanolamine, palmitoyloleoyl phosphatidylethanolamine or dioleoyl phosphatidylethanolamine. Support for these substances may be found at least at column 5 lines 16 - 21.

New dependent claim 23 recites that the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine. Support for dioleoyl phosphatidylethanolamine may be found at least at column 5 lines 19 - 20.

New dependent claim 24 recites that the headgroup derivatized lipid comprises a dicarboxylic acid selected from glutaric acid, sebacic acid, succinic acid or tartaric acid. Support for these groups may be found at least at column 6 line 41 - 52.

New dependent claim 25 recites that the dicarboxylic acid of claim 24 is glutaric acid. Support for glutaric acid may be found at least at column 6 line 44.

New dependent claim 26 recites that the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine and glutaric acid. Support for these substances may be found at least at column 6 line 44 and column 5 lines 19 - 20.

New dependent claim 27 recites that the  $R_1$  from Claim 17 is  $(CH_2)_nCH_3$  and Z of claim 17 is C(O)O. Support for C(O)O may be found at least at column 4 line 24.

New dependent claim 28 recites that the  $R_1$  from Claim 17 is  $(CH_2)_{n1}CH_3$  and Z of claim 17 is NH. Support for NH may be found at least at column 4 line 22.

New dependent claim 29 recites that the  $R_1$  from Claim 17 is  $(CH_2)_{n1}CH_3$  and Z of claim 17 is HNC(O). Support for HNC(O) may be found at least at column 4 line 22.

New dependent claim 30 recites an additional bioactive agent. Support for bioactive agents may be found at least at column 7 lines 16 - 57.

New dependent claim 31 recites pharmaceutical compositions based on the liposome of claim 17. Support for pharmaceutical compositions may be found at least at column 7 line 8 - 33.

7. That we believe the original patent to be partly inoperative or invalid due to typographical errors in the specification and in Claim 1. In Claim 1 (column 11 line 42) the letter "n" was omitted from in front of the number 8. Clearly this was a typographical error; the applicant intended to assign a value of either zero or 1 to the variable  $n_8$  in the formula recited in claim 1. Likewise in the specification (column 4 line 8) the same correction was made. In addition, in the specification (column 3 line 66) the variable  $Y_1$  was inadvertently assigned the designation  $y_1$ . A cut up version of the Letters Patent is being submitted with these corrections included.

8. That the above identified reissue patent application was filed within two years of the issue date of the original patent and so broader claims than those in the issued patent are permissible.

9. That all errors being corrected in the above-identified reissue application arose without any deceptive intention on the part of the applicants.

10. That we hereby appoint the following attorneys to prosecute the presently filed reissue patent application and to transact all business in the Patent and Trademark Office connected therewith:

Gerald F. Swiss, Registration No. 30,113  
Teresa Stanek Rea, Registration No. 30,427  
Robert G. Mukai, Registration No. 28,531  
Mary Ann Dillahunty, Registration No. 34,576  
Mercedes K. Meyer, Registration No. 44,939  
Julie L. Heinrich, Registration No. 48,070

Address all correspondence to:

Gerald F. Swiss  
Burns Doane Swecker & Mathis, LLP  
P.O. Box 1404  
Alexandria, Virginia 22313-1404

Address all telephone calls to Gerald F. Swiss at (650) 622-2300.

11. That we further declare that all statements made herein on our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dated: \_\_\_\_\_

By: \_\_\_\_\_

Eric Mayhew

By: \_\_\_\_\_

Andrew S. Janoff

By: \_\_\_\_\_

Imran Ahmad

By: \_\_\_\_\_

Suresh Bhatia

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